DEC 11 1997

510(k) SUMMARY
GREATBATCH SCIENTIFIC MR COMPATIBLE LAPAROSCOPE AND OPERATING LAPAROSCOPE

K972280

Submitter Name:	Greatbatch Scientific a division of Wilson Greatbatch Ltd.
Submitter Address:	4100 Barton Road Clarence, New York 14031
Contact Person:	Gary J. Sfeir, RAC
Phone Number:	716.759.5277
Facsimile Number:	716.759.5280
Date Prepared:	8 December, 1997
Device Trade Name:	Greatbatch Scientific MR Compatible Laparoscope and Operating Laparoscope
Device Common Name:	Laparoscope
Classification Name:	Laparoscope
Predicate Devices:	Optus Laparoscope and Operating Laparoscope
Device Description:	The Greatbatch Scientific MR Compatible Laparoscope and Operating Laparoscopes are available in standard and autoclavable 8.0mm, 10.0mm sizes, with 0°, 30° or 45° angles.
Intended Use:	For use to permit direct viewing of the organs within the peritoneal cavity for the purpose of performing diagnostic and surgical procedures in a MR or an interventional MR environment, not to exceed a 1.5 Tesla static magnetic field.
Device Technological Characteristics and Comparison to Predicate Devices(s):	The device technological characteristics are similar in design to the predicate device.
Performance Data:	The device was tested for MR Compatibility and was found to be acceptable for use in a 1.5 Tesla static magnet field. See attached MR Safety Testing summary.
Conclusion:	The Greatbatch Scientific MR Compatible Laparoscope and Operating Laparoscope as designed, can be used in a MR or an interventional MR environment, not to exceed a 1.5 Tesla static magnetic field.

GREATBATCH SCIENTIFIC
MR COMPATIBLE LAPAROSCOPE
MR SAFETY TESTING SUMMARY

A Greatbatch Scientific MR Compatible 8.0mm endoscope was tested in conjunction with a 1.5 Tesla GE Signa Magnet for the presence of magnetic attraction and torque, artifact, and RF Heating. Based on intended use of the device and the results of extensive MR safety testing listed below, this device is MR Compatible.

1. Magnetic Attraction and Torque

Static field strength-	1.5 Tesla / GE Signa 64 MHz MR System
Type of test-	String deflection
Observed deflection -	Very slight
Observed torque -	5 degrees

2. Artifact

Static field strength -	1.5 Tesla / GE Signa 64 MHz MR System
Sequences -	1
Amount of distortion:	

Sequence	axial plane	sagittal plane
FSPGR	++	++

++ artifact same as the device

3. RF Heating

A. Phantom:

Type of phantom -	A 50 lb., fluid filled rectangular shaped plastic Plexiglas phantom
Type of RF Coil -	Body coil
SAR applied -	2.1 W/kg
Length of time -	60 minutes
Maximum temperature rise observed -	0.5°C

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Gary J. Sfeir, RAC
Director, Regulatory Affairs
Greatbatch Scientific
4100 Barton Road
Clarence, New York 14031

Re: K972280
Trade Name: Greatbatch Scientific MR Compatible Laparoscopes and Operating Laparoscopes
Regulatory Class: II
Product Code: GCJ
Dated: September 10, 1997
Received: September 12, 1997

Dear Mr. Sfeir:

We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined the devices are substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the devices, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval), they may be subject to such additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements , as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. In addition, FDA may publish further announcements concerning your devices in the Federal Register. Please note: this response to your premarket notification submissions does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your devices, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Device Technological Characteristics and Comparison to Predicate Devices(s):	The device technological characteristics are similar in design to the predicate device.
Performance Data:	The device was tested for MR Compatibility and was found to be acceptable for use in a 1.5 Tesla static magnet field. See attached MR Safety Testing summary.
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MR COMPATIBLE LAPAROSCOPE
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Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4

INDICATIONS FOR USE

510 (k) Number (if known): K972280

Device Name: **Greatbatch Scientific MR Compatible Laparoscopes and Operating Laparoscopes**

Indications For Use:

The Greatbatch Scientific MR Compatible Laparoscopes and Operating Laparoscopes are used to permit viewing of the organs within the peritoneal cavity for the purpose of performing diagnostic and surgical procedures in a MR or an interventional MR environment, not to exceed a shielded 1.5 Tesla magnet.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

CONCURRENCE OF CDRH; OFFICE OF DEVICE EVALUATION (ODE)

PRESCRIPTION USE X OR... OVER-THE-COUNTER USE _____

(Division Sign-Off) Division of General Restorative Devices

510(k) Number K972280

(OPTIONAL FORMAT 1-2-96)